IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

YOLANDA J. JAMES,	**:**	**No. 1:10-CV-2082**
Plaintiff	**:**	
	:	**(Chief Judge Kane)**
v.	**:**	
	:	
STRYKER CORPORATION and	**:**	
STRYKER SALES CORPORATION,	**:**	
Defendants	**:**	

MEMORANDUM ORDER

Pending before the Court is Defendants' motion to dismiss Count III of Plaintiff's amended complaint. (Doc. No. 18.) In their motion, Defendants argue that they are entitled to judgment as a matter of law on Plaintiff's fraud claim, because Pennsylvania law requires that failure to warn claims involving prescription medical devices be analyzed using a negligence framework. (Id. ¶¶ 3-4.) In response, Plaintiff states that her fraud claim is not based on either a failure to warn or a "failure to disclose material safety information" theory. (Doc. No. 21 at 7.) Instead, Plaintiff asserts that her fraud claim arises out of Defendants perpetrating a fraud upon the medical community and Plaintiff by means of unlawful, off-label promotions. (Id.) Because the Court agrees with Plaintiff that her fraud claim is not based on a failure to warn theory, the Court will deny Defendants' motion to dismiss Count III of Plaintiff's amended complaint.

I. BACKGROUND[1]

Plaintiff underwent routine arthroscopic surgery on her left shoulder in October 2004. (Doc. No. 10 ¶ 22.) Following Plaintiff's surgery, her physician affixed a pain pump

[1] The Court notes that its jurisdiction is founded on 28 U.S.C. § 1332. Plaintiff is a citizen of Pennsylvania, Defendants are Michigan corporations, and the amount-in-controversy exceeds $75,000.

manufactured by Defendants Stryker Corporation and Stryker Sales Corporation ("Defendants") which "continuously infused [an] anesthetic directly into her shoulder joint for approximately 48 hours following her surgery." (Id.) Plaintiff claims that "[t]he continuous injection of anesthetic drugs over time directly into [her] shoulder joint after her . . . surgery subsequently caused her serious and permanent cartilage damage." (Id. ¶ 27.) Plaintiff's complaint contains three separate causes of action against Defendants based on negligence (Count I), negligent misrepresentation (Count II), and fraud (Count III).

At issue in the motion to dismiss is Plaintiff's fraud claim. Plaintiff alleges that Defendants' and their agents "made material misrepresentations to Plaintiff, Plaintiff's physicians, and to the public that pain pumps and the anesthetics used in the pumps were safe for use following shoulder surgeries." (Doc. No. 10 ¶ 93.) Despite Defendants' knowledge that the FDA had not approved the pain pump for such uses, Defendants "marketed these products off-label through direct representation to end users and promotional materials. (Id. ¶¶ 95-99.) Plaintiff alleges that:

> [Defendants] further misled both the medical community and the public at large, including the Plaintiff herein, by making false representations about the safety of its products. The Defendants downplayed, understated and/or disregarded their knowledge of the serious and permanent side effects associated with the use of their products, despite the existence of information available to Defendants that should have demonstrated that Stryker products were likely to cause serious injuries to product users.
>
> . . . When Stryker's agents and sales representatives made the foregoing representations, they knew those representations were false, deceptive, and misleading, and they made those false representations with the intent to defraud, deceive, and mislead.

(Doc. No. 10 ¶¶ 103-04.)

II. STANDARD OF REVIEW

A motion to dismiss pursuant to Rule 12(b)(6) tests the legal sufficiency of the complaint, Kost v. Kozakiewicz, 1 F.3d 176, 183 (3d Cir. 1993). In reviewing a motion to dismiss, a court may "consider only the allegations in the complaint, exhibits attached to the complaint, matters of public record, and documents that form the basis of a claim." Lum v. Bank of Am., 361 F.3d 217, 221 n.3 (3d Cir. 2004). The motion will only be properly granted when, taking all factual allegations and inferences drawn therefrom as true, the moving party is entitled to judgment as a matter of law. Markowitz v. Ne. Land Co., 906 F.2d 100, 103 (3d Cir. 1990). The burden is on the moving party to show that no claim has been stated. Johnsrud v. Carter, 620 F.2d 29, 33 (3d Cir. 1980). Thus, the moving party must show that Plaintiff has failed to "'set forth sufficient information to outline the elements of his claim or to permit inferences to be drawn that [those] elements exist.'" Kost, 1 F.3d at 183 (citation omitted). A court, however, "need not credit a complaint's 'bald assertions' or 'legal conclusions' when deciding a motion to dismiss." Morse v. Lower Merion Sch. Dist., 132 F.3d 902, 906 (3d Cir. 1997). Indeed, the Supreme Court has recently held that while the 12(b)(6) standard does not require "detailed factual allegations," there must be a "showing, rather than a blanket assertion, of entitlement to relief. . . . [F]actual allegations must be enough to raise a right to relief above the speculative level." Phillips v. Cnty. of Allegheny, 515 F.3d 224, 231-32 (3d Cir. 2008) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 & n.3 (2007)) (internal quotation marks omitted). Put otherwise, a civil complaint must "set out 'sufficient factual matter' to show that the claim is facially plausible." Fowler v. UPMC Shadyside, 578 F.3d 203, 210 (3d Cir. 2009) (quoting Ashcroft v. Iqbal, 129 S. Ct. 1937, 1949 (2009)); see also In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1418 (3d Cir. 1997) (noting that even though the Third Circuit Court of Appeals has adopted a

"relaxed application" of Rule 9(b)'s heightened pleading requirement of fraud claims "where the factual information is peculiarly within the defendant's knowledge or control," "boilerplate and conclusory allegations will not suffice").

III. DISCUSSION

In the motion to dismiss presently pending before the Court, Defendants challenge Count III of Plaintiff's amended complaint. Defendants argue that Count III constitutes a failure to warn claim masquerading as an allegation of fraud. (Doc. No. 18 at 6-7.) Because Pennsylvania law only permits failure to warn claims against medical device manufacturers to proceed where a Plaintiff establishes negligence, Defendants conclude that Plaintiff's claim must fail. (Id.) Plaintiff counters that because Count III alleges overt fraudulent acts rather than merely fraudulent omissions, Plaintiff has properly stated a claim of fraud and Defendants' motion to dismiss must fail. (Doc. No. 21 at 5.)

Defendants are correct that Plaintiff would be required to demonstrate negligence to state a claim on a failure to warn theory. In Hahn v. Richter, 673 A.2d 888 (Pa. 1996), the Pennsylvania Supreme Court concluded that a plaintiff cannot recover under the strict liability theory outlined in Section 402A of the Restatement in failure to warn suits against a prescription drug manufacturer. Id. at 890-91. Rather, the Hahn court held that a plaintiff may only recover for a failure to warn under the standard articulated in Section 388 of the Restatement. Id. That section limits recovery in failure to warn cases to those circumstances in which the manufacturer "fails to exercise reasonable care" to warn the consumer. Restatement (Second) of Torts § 388(c) (1965). The Pennsylvania Superior Court extended the holding articulated in Hahn to include medical device cases. Creazzo v. Medtronic, Inc., 903 A.2d 24, 31 (Pa. Super. Ct. 2006).

In the present case, Defendants' reliance on Hahn and Creazzo does not advance their cause of challenging the fraud claim in Plaintiff's amended complaint. Plaintiff does not attempt to state a claim for failure to warn in Count III. Rather, Plaintiff alleges that Defendants committed fraud by, inter alia, promoting their products for uses that had been expressly rejected by the FDA. (Doc. No. 10 ¶¶ 96-104); see also Colaizzi v. Beck, 895 A.2d 36, 39 (Pa. Super. Ct. 2006) (stating that in Pennsylvania, to establish common law fraud, a plaintiff must allege: (1) misrepresentation of a material fact; (2) scienter; (3) intention by the declarant to induce action; (4) justifiable reliance by the party defrauded upon the misrepresentation; and (5) damage to the defrauded party proximately caused by the reliance). According to Plaintiff's amended complaint, Defendants and their agents misrepresented to Plaintiff and her physicians that pain pumps and the anesthetics used in the pumps were safe for use following shoulder surgeries. (See Doc. No. 10 ¶ 93.) Defendants knew that the FDA had not approved the pain pump for off-label uses, yet they continued to market the product for such uses. (Id. ¶¶ 95-99.) Plaintiff and her physicians relied on these misrepresentations, used Defendants' pain pump, and Plaintiff's injury resulted. (Id. ¶¶ 105-07.) Therefore, Plaintiff has stated a cognizable fraud claim which, as a matter of law, is distinct from a failure to warn claim.[2] See, e.g., Soufflas v. Zimmer, Inc., 474 F. Supp. 2d 737, 750-53 (E.D. Pa. 2007) (addressing fraud and failure to warn claims as separate and distinct claims in a medical device case).

[2] The Court notes that Plaintiff's allegations that Defendants made fraudulent misrepresentations to Plaintiff and her physicians are also distinct from a claim that Defendants made fraudulent misrepresentations to the FDA. Allegations of "fraud-on-the agency" are preempted by the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. See Buckman Co. v. Plaintiff's Legal Comm., 531 U.S. 341, 348 (2001) ("[W]e hold that the plaintiffs' state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law.").

The cases relied upon by Defendants in which fraud claims were dismissed are readily distinguishable. In those cases, the plaintiffs alleged that the defendants committed fraud by failing to disclose dangers. See, e.g., Kester v. Zimmer Holdings, Inc., No. 2:10-cv-00523, 2010 U.S. Dist. LEXIS 110403, at *13 (W.D. Pa. Oct. 18, 2010); Kline v. Pfizer, Inc., No. 08-3238, 2009 U.S. Dist. LEXIS 623, at *4-10 (E.D. Pa. Jan. 6, 2009). Those courts concluded that a "failure to disclose" claim was indistinguishable from a "failure to warn" claim. Kester, 2010 U.S. Dist. LEXIS 110403, at *13; Kline, 2009 U.S. Dist. LEXIS 623, at *10-11. However, those courts did not hold that all claims of fraud were barred in medical device cases.[3] To the contrary, in Kline, upon which Defendants heavily rely, the court rejects Defendants' position, concluding:

> [Plaintiff] cites [Clark v. Pfizer, No. 1819, 2008 Phila. Ct. Com. Pl. LEXIS 74 (Mar. 14, 2008),] for the proposition that a plaintiff can maintain a fraud claim against a prescription drug manufacturer. However, Clark is inapposite to the present case because the theory of liability there was not based upon failure to warn, but rather on the manufacturer's promotion of unapproved uses of the drug.

Kline, 2009 U.S. Dist. LEXIS 623, at *12. Here, Plaintiff alleges that Defendant marketed a product to be used in a manner that the FDA expressly rejected. As such, Plaintiff alleges overt acts that go beyond a mere failure to warn. Because Defendants identify no law supporting the proposition that Pennsylvania bars claims of fraud in medical device suits, the motion to dismiss

[3] The Court further observes that the purpose in treating medical device cases differently from other failure to warn cases is not served by barring all fraud claims. As explained by the Restatement, medical device cases are treated differently than other failure to warn cases because, although dangerous, where the products "are properly prepared and marketed" the risk of danger is justifiable. Restatement (Second) of Torts § 402A cmt. k (1965). Where a manufacturer fraudulently markets a drug for "off label" uses, the marketing of that product is no longer justified in the way a drug marketed for its approved purposes is.

must fail.

ACCORDINGLY, on this 27th day of January 2011, **IT IS HEREBY ORDERED** that Defendant's motion to dismiss Count III of Plaintiff's complaint, (Doc. No. 19), is **DENIED**.

It is **FURTHER ORDERED** that Document Number 22 filed on January 17, 2011, and titled as Plaintiff's "First Amended Complaint" is **STRICKEN AS DUPLICATIVE**. Plaintiff's first amended complaint is already docketed as Document Number 10. To the extent that Plaintiff wishes to amend her first amended complaint, she must seek the opposing parties' written consent or leave of Court. See Fed. R. Civ. P. 15(a)(2).

S/ Yvette Kane
Yvette Kane, Chief Judge
United States District Court
Middle District of Pennsylvania